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No. 04-477

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IN THE

# Supreme Court of the United States

CHIRON CORPORATION,

*Petitioner,*

v.

GENENTECH, INC.,

*Respondent.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## RESPONDENT'S BRIEF IN OPPOSITION

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## QUESTIONS PRESENTED

1. Whether Section 112 of the Patent Statute requires that a patent application both describe the invention (the written description requirement) and explain how one skilled in the art can make and use it (the enablement requirement), especially in a priority context, where a patentee must rely on the disclosure in an earlier-filed patent application to support an invention claimed in a later-filed patent application.

2. Whether a jury's general verdict should stand when one basis for the verdict is invalidated, but the verdict is required as a matter of law.

## RULE 29.6 CORPORATE DISCLOSURE STATEMENT

ROCHE HOLDINGS INC. owns approximately 59 percent of the issued common stock of Respondent, GENENTECH, INC.; GENENTECH, INC. remains an independent, publicly traded company.

TABLE OF CONTENTS


| | Page |
|---|---|
| QUESTIONS PRESENTED | i |
| RULES 29.6 CORPORATE DISCLOSURE STATEMENT | ii |
| TABLE OF AUTHORITIES | iv |
| STATUTORY PROVISIONS INVOLVED | 1 |
| INTRODUCTION | 1 |
| STATEMENT OF THE CASE | 5 |
| REASONS FOR DENYING THE PETITION | 10 |
| I. IN A PRIORITY CASE, SUCH AS THIS CASE, THE FEDERAL CIRCUIT JUDGES UNANIMOUSLY AGREE THAT THE WRITTEN DESCRIPTION REQUIREMENT IS SEPARATE FROM THE ENABLEMENT REQUIREMENT | 10 |
| II. THE FEDERAL CIRCUIT CORRECTLY APPLIED SETTLED WRITTEN DESCRIPTION PRECEDENT IN THIS FACT-SPECIFIC PRIORITY CASE | 15 |
| III. OTHER GROUNDS REQUIRE AFFIRMANCE OF THE FEDERAL CIRCUIT'S DECISION | 19 |
| IV. THE FEDERAL CIRCUIT'S DECISION DOES NOT IMPLICATE ANY GENERAL VERDICT RULE | 22 |
| CONCLUSION | 24 |

TABLE OF AUTHORITIES

CASES Page

*In re Ahlbrecht*, 435 F.2d 908 (CCPA 1971) ..... 14
*Amgen Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003) ..... 13, 14, 17
*Asbill v. Housing Auth. of Choctaw Nation*, 726 F.2d 1499 (10th Cir. 1984) ..... 23
*Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291 (Fed. Cir. 1999) ..... 19
*B.G. Corp. v. Walter Kidde & Co.*, 79 F.2d 20 (2d Cir. 1935) ..... 17
*Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317 (Fed. Cir. 2002) ..... 11
*In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004) ..... 11
*Davis v. Rennie*, 264 F.3d 86 (1st Cir. 2001) ..... 23
*In re DiLeone*, 436 F.2d 1404 (CCPA 1971) ..... 14
*E.I. duPont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247 (8th Cir. 1980) ..... 23
*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) ..... 12
*Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998) ..... 11, 13
*Kern v. Levolor Lorentzen, Inc.*, 899 F.2d 772 (9th Cir. 1990) ..... 23
*In re Koller*, 613 F.2d 819 (CCPA 1980) ..... 16
*Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306 (Fed. Cir.), *cert. denied*, 124 S. Ct. 464 (2003) ..... 11, 12, 20
*Monrosa v. Carbon Black Exp., Inc.*, 359 U.S. 180 (1959) ..... 19
*Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004) ..... 11
*PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235 (Fed. Cir. 2002) ..... 11
*Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (Fed. Cir. 2000) ..... 13

TABLE OF AUTHORITIES—continued

Page

*In re Ruschig*, 379 F.2d 990 (CCPA 1967) ..... 11

*Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) ..... 11, 13

*Union Pac. R.R. v. Barber*, 356 Ark. 268 (Ark.), *cert. denied*, 125 S. Ct. 320 (2004) ..... 4, 22

*University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir.), *reh'g en banc denied*, 375 F.3d 1303 (Fed. Cir. 2004), *cert. denied*, 73 U.S.L.W. 3247 (U.S. Nov. 29, 2004) (No. 04-476) ..... 1, 10

*Utter v. Hiraga*, 845 F.2d 993 (Fed. Cir. 1988), *superseded on other grounds by Kubota v. Shibuya*, 999 F.2d 517 (Fed. Cir. 1993) ..... 16

*Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991) ..... *passim*

*Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997) ..... 11

*Westphal v. Fawzi*, 666 F.2d 575 (CCPA 1981) ..... 17

STATUTES

35 U.S.C. § 102 ..... 1, 2

§ 112 ..... 6

§ 120 ..... 2, 6

§ 132 ..... 1, 6, 16, 20, 21

RULE

Fed. R. Civ. P. 61 ..... 23

OTHER AUTHORITY

U.S. Dep't of Commerce, *Manual of Patent Examining Procedure* (8th ed. rev. 2004) ..... 6

## STATUTORY PROVISIONS INVOLVED

In addition to the statutory provisions included in the petition, Sections 102 and 132 of Title 35 of the United States Code are relevant. Section 102, in relevant part, provides:

> A person shall be entitled to a patent unless—
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent . . . .

Section 132(a), in relevant part, provides:

> No amendment shall introduce new matter into the disclosure of the invention.

## INTRODUCTION

In its petition, Chiron wrongly argues that this case presents for the Court's review a conflict within the Federal Circuit about whether Section 112 of the Patent Statute requires a patentee to provide a written description of the invention that is separate from an enabling description of the invention. Indeed, in another case, this Court recently denied a petition seeking review of whether written description is a separate requirement of Section 112. *See University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir.), *reh'g en banc denied*, 375 F.3d 1303 (Fed. Cir. 2004), *cert. denied*, 73 U.S.L.W. 3247 (U.S. Nov. 29, 2004) (No. 04-476).

This case is even less worthy of review than *Rochester* because it arises in the priority context—that is, Chiron must rely on an earlier patent application to support an invention it claimed in a later application. The Federal Circuit judges *unanimously* agree that a separate written description requirement exists and is necessary in the priority context.

Accordingly, there is no conflict within the Federal Circuit, and no basis for this Court's review.

This case exemplifies why Congress included a separate written description requirement in Section 112 of the Patent Statute. Here, the written description requirement alone prevented Chiron from later claiming antibodies it did not invent.

In U.S. Patent No. 6,054,561 ("the '561 patent"), Chiron claimed "'[a] monoclonal antibody that binds to human c-erbB-2 antigen.'" Pet. App. 2a. For infringement purposes in this case, Chiron needed the district court to construe broadly the claim term "monoclonal antibody." Chiron therefore convinced the district court to adopt a very broad construction of monoclonal antibody that encompassed murine, chimeric, and humanized monoclonal antibodies that bind the breast cancer antigen HER2.[1] This broad claim construction included Herceptin®, Genentech's humanized monoclonal antibody.

However, Chiron's '561 patent faced an invalidity problem as a result of the district court's broad construction of the claim term "monoclonal antibody." In 1995, when Chiron filed the '561 patent application, murine, chimeric, and humanized antibodies that bind HER2 already were "known or used by others . . . or patented or described in a printed publication." 35 U.S.C. § 102. Unless Chiron could rely on an application with an earlier filing date than 1995, the '561 patent admittedly was invalid under Section 102.

Chiron attempted to circumvent Section 102 by arguing that, under the priority provision of the Patent Statute, 35 U.S.C. § 120, the '561 patent should be given the filing date of a patent application Chiron filed in 1984, or alternatively,

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[1] The terms "c-erbB-2 antigen," used in the '561 patent, and "HER2," as used in the Federal Circuit's opinion and in Chiron's petition, are synonymous. A888, 1153. For consistency, Genentech uses the term "HER2" in this opposition.

the filing date of Chiron's 1985 or 1986 patent applications. To gain the priority advantage of Section 120, Chiron's earlier patent applications had to satisfy the requirements of Section 112.

In pertinent part, Section 112 of the Patent Statute requires that a patent application set forth a "written description of the invention" (the written description requirement), and explain "the manner and process of making and using it" (the enablement requirement). In a priority case, the written description requirement exists separate from the enablement requirement to ensure that a patentee had possession of the full scope of the later-claimed invention on the filing date of the earlier application. This policing function of the written description requirement plays an essential role in priority cases. But for the written description requirement in a priority case, a patentee retroactively could misuse the past to stake claim to the future, as Chiron tried to do here.

Specifically, in 1984 Chiron filed a patent application that disclosed a very narrow invention: a murine monoclonal antibody that bound to an unknown, unidentified antigen found on various breast cancer cells. In contrast, as a result of the district court's claim construction, the '561 patent claims a very broad invention encompassing not only murine, but also chimeric and humanized, monoclonal antibodies that bind HER2. However, Chiron's 1984 application did not describe chimeric and humanized antibodies that bind HER2. Indeed, on the 1984 filing date, Chiron did not even realize either that HER2 was a breast cancer antigen or its importance. HER2 only was first identified in 1985—and not by Chiron. In fact, Chiron eventually learned about HER2 and its importance in breast cancer treatments from Genentech.

Chiron could not claim what it failed to describe in the 1984 patent application. The jury, the district judge, and the Federal Circuit therefore all agreed that Chiron's 1984 application did not satisfy the written description requirement

of Section 112. This result is correct; it is highly fact-specific to the priority context of this case, and it is consistent with law, fairness, and policy.

For at least three reasons, this Court's review also neither would end the case nor dictate a different result. First, Chiron added 70 pages of disclosure to its '561 patent application, triggering Section 132's prohibition against new matter. Chiron's new matter problem is a separate ground for upholding the judgment. Second, even if this Court were to merge the written description and enablement requirements in a priority context, the Federal Circuit's decision still should be affirmed under Section 112. Under any standard, Chiron overreached and claimed as its own in the '561 patent subject matter it did not invent in 1984. Third, Genentech's undecided cross-appeal on claim construction, upon consideration, would result in a much narrower construction of "monoclonal antibody," under which Genentech does not infringe.

Chiron's tagalong general verdict argument also does not merit review. Chiron's primary argument—that its petition presents the same issue presented in *Union Pacific Railroad Company v. Barber*, and should be granted on that basis—is fully answered by the Court's denial of the *Union Pacific* petition. *See Union Pac. R.R. v. Barber*, 356 Ark. 268 (Ark.), *cert. denied*, 125 S. Ct. 320 (2004). Moreover, the question of whether a jury's general verdict should stand when one basis for the verdict is invalidated is not presented in this case because, as the Federal Circuit held, the verdict reached by the jury here was legally required. The same evidence that demonstrated that chimeric and humanized antibodies were not known and did not need to be enabled in 1984 also demonstrated that, as a matter of law, in 1984 Chiron could not satisfy the written description requirement for new matter appearing in the '561 patent.

## STATEMENT OF THE CASE

1. Beginning in the 1980s, Genentech successfully developed its breakthrough breast cancer treatment, Herceptin®: a genetically engineered, humanized antibody that treats one of the most aggressive forms of breast cancer. Herceptin® works by targeting, or binding, the HER2 antigen found on breast cancer cells, and directly inhibiting growth of those cells. A1149-52. Herceptin® is a humanized antibody, *i.e.*, genetically engineered to resemble antibodies naturally produced by the human immune system, and its structure does not trigger a significant adverse immunological response when administered to breast cancer patients. A8340-42, 1146-53. *See also* Pet. App. 7a.

Chiron followed a very different course from Genentech in the 1980s. A1271. Chiron tried to improve the efficacy of conventional murine (mouse) antibodies, which target breast cancer cells, by linking the murine antibodies to a poison. A1187-88, 1191-1200, 1271. Chiron's murine antibodies are structurally and functionally different from Genentech's humanized Herceptin® antibodies. A1128-29, 1276, 1322-24, 1541-42, 3431, 8160, 8203-10, 8220. Of note, the mouse structure of murine antibodies cannot effectively interact with the human immune system, and murine antibodies cannot be used in long-term human therapies without risking toxic shock or death. Pet. App. 4a. A1125, 1185, 1247, 1542, 1755, 3358-59, 8203.

In 1984, Chiron filed the first of three applications based on its work with conventional murine antibodies. The 1984 application disclosed seventeen murine antibodies that target various breast cancer cells, but did not identify or provide other information about the specific antigens found on the various breast cancer cells targeted by the murine antibodies.[2]

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[2] Chiron's 1985 and 1986 patent applications also did not identify the antigens found on the various breast cancer cells targeted by the murine antibodies disclosed in those applications. A1278, 2960-3034.

A1229, 1278, 2929-55. As it turns out, only one of these seventeen antibodies is at all relevant in this case, murine antibody 454C11, which binds an antigen Chiron only much later realized was HER2. A1177-78. The 1984 application claimed a very narrow invention limited to murine antibodies. A1208, 2956-57.

Meanwhile, by 1985, Genentech published detailed information about the HER2 antigen. A1148-49, 2878-85, 3337-44. In 1988, Genentech presented its HER2 work at a conference attended by Chiron scientists. A1229. After the conference, Chiron reviewed its murine antibody data and its 1984, 1985, and 1986 patent applications to see whether HER2 might be one of the antigens Chiron did not identify or describe in those applications. Chiron mistakenly concluded that HER2 was not one of the unidentified antigens, and published a paper saying so. A2744-54, 1230. Chiron did not correct its mistaken conclusion until nearly two years later. A2755-59.

In 1995, Chiron filed a continuation-in-part ("CIP")[3] patent application, which ultimately issued as the '561 patent. A8200-8322, 1739-1801. The '561 patent claimed priority to the filing date of the 1984 application.[4] A8200.

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[3] A CIP application continues the disclosure of an earlier-filed application, but also adds new matter not found in the earlier application. Claims in a CIP application that are limited to matter disclosed in the earlier-filed application are entitled to the earlier application's filing date. However, claims in a CIP application that encompass both original matter disclosed in the earlier application and new matter added in the CIP application are only entitled to the filing date of the later, CIP application. *See* 35 U.S.C. §§ 112, 120, 132; *see also* U.S. Dep't of Commerce, *Manual of Patent Examining Procedure* § 201.08 (8th ed. rev. 2004) (reproduced in relevant part in the appendix to this opposition brief. App., *infra*, 5a-8a).

[4] The '561 patent also claimed priority to Chiron's 1985 and 1986 applications. The Federal Circuit affirmed the jury verdict that the '561 patent is not entitled to the filing date of the 1985 or the 1986 application. Pet. App. 2a, 9a. Chiron does not challenge that ruling.

Chiron's 1995 CIP application contained over 70 pages of new matter. A8200-8228, 8249-8322. These 70 pages added much more than a "list of examples of antibodies," as Chiron alleges. Pet. 4. In these pages, Chiron described for the first time in a patent application: (1) the identity of the previously unknown, undescribed antigen bound by murine antibody 454C11 as HER2; (2) the chemical structures of chimeric and humanized antibodies, which are distinct from the chemical structures of murine antibodies; (3) the various advantages that chimeric and humanized antibodies have over conventional murine antibodies; and (4) how to make chimeric and humanized antibodies. A8200-8228, 8249-8322.

Genentech's highly successful human clinical trials of Herceptin® became public during Chiron's prosecution of its 1995 CIP application in the Patent and Trademark Office ("PTO"). A1209. At that point, Chiron amended its claims in an effort to obtain broad claims to humanized, genetically engineered antibodies. A2680-83. The PTO rejected Chiron's attempts because the priority applications did not include Section 112 support for such claims. A2720, 8354. Eventually, the PTO issued the '561 patent with claims directed to a "monoclonal antibody." A1794-95, 2674.

2. Following issuance of the '561 patent, Chiron sued Genentech, alleging that Herceptin® infringed the '561 patent. A8958-62. Herceptin® is a humanized antibody. Therefore, to prove infringement, Chiron pursued and successfully obtained a very broad construction of "monoclonal antibody," which explicitly included murine, chimeric, and humanized antibodies. Pet. App. 7a. Based on this broad claim construction, the district court summarily ruled that Herceptin® infringed the '561 patent. *Id.* at 7a, 72a.

For purposes of the trial, Genentech had to accept Chiron's broad claim construction, and contest only the *validity* of the '561 patent. Genentech challenged Chiron's priority claim to the 1984, 1985, and 1986 patent applications on the grounds

that none of the earlier applications described or enabled the broadly construed "monoclonal antibody" invention claimed in the '561 patent, as required by Sections 112 and 120. Chiron admitted that intervening publications would invalidate the '561 patent unless Chiron's 1984, 1985, or 1986 patent applications provided a written description and enablement of the invention claimed in the '561 patent. Pet. App. 7a.

3. In the trial court:

> the thirteen-day jury trial adjudicated only whether any of the priority applications satisfy the written description and enablement requirements of 35 U.S.C. § 112, first paragraph. Specifically the trial determined whether the 1980s applications adequately disclosed, and thus supported, the claim to chimeric and humanized antibodies claimed in the '561 patent (with its filing date in 1995). The jury determined that Genentech proved by clear and convincing evidence that none of the applications satisfy both the written description and the enablement requirement for the subject matter in the '561 patent's claims.

Pet App. 7a-8a. Following the verdict, the district court denied Chiron's post-trial motions and entered a judgment of invalidity of the '561 patent. *Id.* at 8a.

4. Chiron appealed to the Federal Circuit. The Federal Circuit unanimously affirmed the district court's denial of Chiron's post-trial motions. Pet. App. 2a. The Federal Circuit examined Chiron's priority applications for compliance with the separate written description and enablement requirements of Section 112, in accordance with settled precedent. *Id.* at 9a. The court affirmed "because neither the 1985 nor the 1986 application enables the claims of the '561 patent." *Id.* Moreover, "[t]he 1984 application does not support the new matter added to the '561 patent and thus does not satisfy the written description requirement." *Id.*

The district court's claim construction controlled the Federal Circuit's enablement and written description rulings.[5] The court understood that this "claim construction reads the claims of the '561 patent to embrace not only murine antibodies but also chimeric and humanized antibodies that bind HER2." Pet. App. 11a. The court started with chimeric antibodies, observing that, "[i]f the applications in this case do not enable or provide new matter support for chimeric antibodies, this court need not proceed to examine humanized antibodies." *Id.* at 12a.

The Federal Circuit ruled that "the first publication documenting the successful creation of chimeric antibodies occurred after the filing of the 1984 application" and that "the record conclusively supports that the Chiron scientists did not possess and disclose this technology in the February 1984 filing." Pet. App. 12a-13a.[6] Hence, Chiron did not describe chimeric antibodies in its 1984 application. The Federal Circuit therefore held that "the '561 patent cannot claim priority based on the 1984 application because it fails to comply with the written description requirement." *Id.* at 13a.

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[5] Indeed, the Federal Circuit plainly understood that the district court's very broad claim construction, which Chiron proposed in the first instance and did not appeal, compelled an affirmance. As the Federal Circuit explained, it would have faced a "dilemma" if required to consider claim construction because only a portion of the meaning of "monoclonal antibody" as used in the '561 patent can claim priority to the 1984 application. The "dilemma" would be:

> Either construe the term according to the meaning of the earliest application but contrary to the explicit definition in the '561 patent or construe the term according to the explicit definition in the '561 patent but broader than the disclosure of the earliest application . . . . [T]he latter alternative would run afoul of the prohibition against importing new matter into later patent documents.

Pet. App. 19a-20a.

[6] Moreover, "the first publication to disclose humanized antibodies appeared in May 1986," Pet. App. 5a, and Chiron also did not possess or disclose humanized antibodies in the 1984 application. A2929-59.

In a concurring opinion, Judge Bryson opined that the 1984 application did not satisfy either the written description or the enablement requirement. Pet. App. 27a. As he explained, Chiron had not sought to "preserve the validity of its ['561 patent] claims by construing them in accordance with the state of the technology at the time of the invention," which Chiron alleged to be 1984. *Id.* at 30a. Instead, Chiron argued "that the 1984 application provide[d] support for claims covering technology that was not in existence" in 1984. *Id.* Thus, Judge Bryson concluded that where, as here, "claims are accorded a scope that exceeds the scope of enablement, [he] would hold that the claims are not entitled to priority as of 1984, not only because of a failure to satisfy the written description requirement, but also because the 1984 application does not enable the asserted claims." *Id.* at 30a-31a.

5. Chiron filed a petition for rehearing or rehearing *en banc*. The Federal Circuit denied Chiron's petition without comment or dissent.[7]

## REASONS FOR DENYING THE PETITION

### I. IN A PRIORITY CASE, SUCH AS THIS CASE, THE FEDERAL CIRCUIT JUDGES UNANIMOUSLY AGREE THAT THE WRITTEN DESCRIPTION REQUIREMENT IS SEPARATE FROM THE ENABLEMENT REQUIREMENT.

Chiron argues that its petition presents the same written description issue as presented in the *Rochester* petition. Pet. 10. This Court denied the *Rochester* petition on November 29, 2004, *Rochester*, 358 F.3d 916 (Fed. Cir. 2004), *cert.*

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[7] Shortly before filing the petition for rehearing or rehearing *en banc* in this case, Chiron's counsel (Morrison & Foerster) also filed a petition for rehearing or rehearing *en banc* raising the same issue, on behalf of the University of Rochester in *Rochester*. The Federal Circuit also denied the *Rochester* petition.

*denied*, 73 U.S.L.W. 3247 (U.S. Nov. 29, 2004) (No. 04-476), and it should deny this petition as well. In fact, the written description issue in this case is even less worthy of review than in *Rochester*.

The patentee in *Rochester* relied solely on the filing date of the application from which the patent in suit issued. Therefore, the issue in *Rochester* was whether the original and only application described and enabled the claimed invention. In contrast, Chiron claimed priority to an application it filed in 1984, requiring a showing that its 1984 application described and enabled the invention Chiron later claimed in the '561 patent.

In the priority setting of this case, the Federal Circuit judges unanimously agree that there is a separate written description requirement. This unanimity is a strong reason for this Court to deny Chiron's petition. This Court leaves the refinement of the patent laws to the Federal Circuit's "sound judgment in [the] area of its special expertise." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). Here, in the sound judgment of every active judge sitting in the Federal Circuit, a separate written description requirement applies in priority cases. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560-64 (Fed. Cir. 1991); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-80 (Fed. Cir. 1998); *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1321 (Fed. Cir. 2002); *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir. 2002); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319-21 (Fed. Cir.) (per curiam), *cert. denied*, 124 S. Ct. 464 (2003); *In re Curtis*, 354 F.3d 1347, 1351-52 (Fed. Cir. 2004); *Noelle v. Lederman*, 355 F.3d 1343, 1348-49 (Fed. Cir. 2004).

Moreover, no "[l]ongstanding [d]ivision," Pet. 13, exists among the judges on this issue. Indeed, the written description requirement of Section 112 has served a priority

policing function since the Federal Circuit's predecessor, the Court of Customs and Patent Appeals, first applied the requirement in a priority case more than thirty years ago. *See In re Ruschig*, 379 F.2d 990, 995-96 (CCPA 1967). Since that time, the Federal Circuit consistently has applied the written description requirement separate from the enablement requirement. The court has not done so merely as a matter of precedent, as Chiron argues. Pet. 14. Rather, the Federal Circuit applies the two requirements separately because the statute requires it: "[t]his court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. § 112, first paragraph, requires a 'written description of the invention' which is separate and distinct from the enablement requirement." *Vas-Cath*, 935 F.2d at 1563-64.[8]

In a footnote, Chiron attempts to disavow the commonly held view of the Federal Circuit judges on the written description requirement in the priority context. Thus, Chiron relies on a comment of Judge Bryson. Pet. 12 n.6. Judge Bryson, however, never has argued that there is no separate written description requirement in a priority context. On the contrary, Judge Bryson has suggested that neither Section 112 nor Section 120 provides a principled reason for *limiting* the written description requirement to priority cases. *Moba*, 325 at 1327-28 (Bryson, J., concurring). Significantly, Judge

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[8] Although this Court has never addressed the written description requirement expressly, it has endorsed the notion of a separate statutory written description requirement:

> [A] number of statutory requirements must be satisfied before a patent can issue. The claimed subject matter must be useful, novel, and not obvious. In addition, the patent application must describe, enable, and set forth the best mode of carrying out the invention. These latter requirements must be satisfied before issuance of the patent . . . . What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue.

*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (internal citations omitted).

Bryson agreed in this priority case that the 1984 application did not satisfy the written description requirement for the '561 patent. Pet. App. 2a, 27a.

The Federal Circuit's uniform and established application of the written description requirement in priority cases is required not only by the text of Section 112, but also by its purpose. In a priority context, "[t]he purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath*, 935 F.2d at 1563-64. To show possession of the invention, the written description requirement requires that a patentee "'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" *Id.* at 1561.

Ensuring possession of a later-claimed invention at the time of the earlier filing date precludes a patent applicant from overreaching and later trying to embellish the true scope of the invention. *See Tronzo*, 156 F.3d at 1158; *see also Amgen Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). "[T]he written description is the metric against which a subsequently added claim is measured to determine if it is due the priority date of the original patent." *Moba*, 325 F.3d at 1319. *See also Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1327 (Fed. Cir. 2000) (later claim to a particular species invalid for inadequate description of that species); *Gentry Gallery*, 134 F.3d at 1480 (patent invalid because narrow description of invention did not support broad, later-drafted claims); *Tronzo*, 156 F.3d at 1159-60 (earlier patent application described only a single cup shape and did not support later claims to genus of cup shapes).

Moreover, Chiron is wrong that the enablement requirement of Section 112 alone can adequately "ensur[e] that an earlier priority date is not improperly attained." Pet. 12 n.6. Indeed, the Federal Circuit recognizes that the enablement requirement "is often more indulgent than the written description requirement." *Amgen*, 314 F.3d at 1334. "[I]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention." *In re DiLeone*, 436 F.2d 1404, 1405 (CCPA 1971). This could occur, for example, "where the specification discusses *only* compound A and contains *no* broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described." *Id.* at 1405 n.1, discussing *In re Ahlbrecht*, 435 F.2d 908, 911 (CCPA 1971) (although the disclosure of the parent application may have enabled production of claimed esters having 2-12 methylene groups, it only described esters having 3-12 methylene groups).

This case also demonstrates the danger of relying solely on enablement to police priority. "Here, the scope of the claim includes not only murine but also chimeric antibodies. While Chiron's applications certainly enable murine antibodies, they do not enable chimeric antibodies." Pet. App. 15a. But, "this new technology [chimeric antibodies] arose after the [1984] filing date and thus was, by definition, outside the bounds of the enablement requirement." *Id.* at 12a. By contrast, when Chiron filed the 1985 and 1986 applications, chimeric and humanized antibodies were known. *Id.* at 14a. However, Chiron still did not disclose anything about chimeric and humanized antibodies in the 1985 and 1986 applications. *Id.* at 15a. Hence, the Federal Circuit agreed with the jury and district court that the 1985 and 1986 applications were non-enabling, while concluding that the 1984 application was enabled as a matter of law. *Id.* at 13a. Without a separate written description requirement to police priority, a patent

applicant, such as Chiron, could obtain the benefit of broader claims by disclosing less. This absurd result is yet a further reason why the petition in this case should be denied.

## II. THE FEDERAL CIRCUIT CORRECTLY APPLIED SETTLED WRITTEN DESCRIPTION PRECEDENT IN THIS FACT-SPECIFIC PRIORITY CASE.

Chiron also advances a series of arguments that the Federal Circuit's decision interprets and applies the written description requirement in ways that contravene decisions of this Court and the Federal Circuit. Chiron is wrong in all respects.

1. Chiron first mistakenly argues that the Federal Circuit's decision is inconsistent with judicial decisions allowing patent protection for both an initial invention and a subsequent improvement of that initial invention. Pet. 21-23. According to Chiron, its 1984 application disclosed a patentable "invention," and Genentech's development of Herceptin® constituted a later patentable "improvement" of Chiron's invention. *Id.* at 23. However, no patent for Herceptin®, or any other alleged "improvement" patent, is at issue in this case. Rather, only Chiron's '561 patent is at issue. The validity of the '561 patent depends on whether Chiron's 1984 application described and enabled the *same* invention that it tried to claim over a decade later in the '561 patent. This case does not involve an invention and its improvement. Therefore, the "more than 100 years" of this Court's precedent about improvement patents, *id.* at 21, is irrelevant here.

Chiron also warns that invalidating the '561 patent "leaves respondent as the sole supplier" of genetically engineered antibodies that treat breast cancer. Pet. 23. Yet, Chiron has never made a commercial product that embodies the technology encompassed by the '561 patent. Nor has Chiron licensed the '561 patent to any entity that is producing a

commercial product. Already, Genentech is the "sole supplier." Had Chiron prevailed, Chiron could have removed the sole supplier from the market.

2. Chiron next argues incorrectly that the Federal Circuit's decision conflicts with a laundry list of case law applying the written description requirement. Pet. 23. The Federal Circuit did not require Chiron to describe "all potential uses" of an invention, as Chiron alleges. *Id.* In the first place, chimeric and humanized antibodies are chemical structures, not "potential uses." Moreover, the Federal Circuit properly required a description in the 1984 application of chimeric and humanized antibodies, which are structurally and functionally distinct species of antibodies explicitly within the scope of the genus of monoclonal antibodies claimed in the '561 patent. Pet. App. 11a. Thus, consistent with *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988), and *In re Koller*, 613 F.2d 819, 823 (CCPA 1980), cited by Chiron, Pet. 23, the Federal Circuit ruled that the single murine antibody species disclosed in Chiron's 1984 application did not adequately describe the broad genus claimed in the '561 patent. Pet. App. 13a-14a.

In addition, contrary to Chiron's assertions, the Federal Circuit did not require Chiron's 1995 application to disclose "future developments," but instead, properly required that Chiron's 1984 *priority* application describe the invention Chiron *later claimed* in its '561 patent. *See Vas-Cath*, 935 F.2d at 1560-63. The 1984 application's narrow disclosure of murine antibodies that target an unknown antigen did not describe the invention Chiron later claimed, a genus of murine, chimeric, and humanized antibodies that target HER2. Therefore, the Federal Circuit affirmed the invalidity finding.

Moreover, the Federal Circuit did not impose an impossible standard for satisfying the written description requirement, but rather, simply and correctly applied the written description requirement consistent with the statutory prohibition against new matter. 35 U.S.C. § 132(a). Under

Section 132, if a claim relies on new matter to satisfy the requirements of Section 112, then the priority date of that later claim is limited to the filing date on which the patent applicant first presented the new matter support. *See, e.g., Westphal v. Fawzi*, 666 F.2d 575, 577 (CCPA 1981). Here, where the invention claimed in the '561 patent relies on and explicitly encompasses new matter (*i.e.*, chimeric and humanized antibodies that bind HER2), the '561 patent is only entitled to priority to the date on which Chiron first presented the new matter support, *i.e.*, the filing date of the 1995 application. For this reason, Chiron's reliance on *Amgen Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), is misplaced.

Chiron's reliance on regional circuit law predating creation of the Federal Circuit is similarly misguided. Judge Hand did not address the written description requirement in *B.G. Corp. v. Walter Kidde & Co.*, 79 F.2d 20 (2d Cir. 1935). Instead, Judge Hand addressed the *novelty* of a spark plug invention. *Id.* at 22 ("Judged by that standard this combination was surely an invention.") In the portion of the opinion Chiron quotes, Judge Hand merely clarified that the inventor of a novel composition is not required to understand all applications of that invention. *Id.*; Pet. at 23-24. *B.G. Corp.* is irrelevant.

Chiron nonetheless argues, relying on *B.G. Corp.*, that its patent should cover all future uses of monoclonal antibodies that bind HER2. Pet. 23-24. The genetically engineered antibodies claimed in the '561 patent, however, are not simply "future uses," nor are they "improvements," "ancillary methods for making improved antibodies," or "'future embodiment[s].'" *Id.* at 21-28. The record presents more than substantial evidence that chimeric and humanized antibodies are structurally and functionally distinct from murine antibodies. *See supra* at 5-6. Chimeric and humanized antibodies are so different from murines that Chiron dedicated more than 70 pages of new disclosure in the

1995 CIP application to describing these new types of genetically engineered antibodies. *See supra* at 7.

3. Chiron's argument that the Federal Circuit's decision reduces incentives for innovation by failing to recognize the role of specific innovation in later technological improvements again ignores the Federal Circuit's holding. The Federal Circuit did not uphold the invalidity of the '561 patent because a "later inventor used a new method, humanization, for making improved monoclonal antibodies that bind to HER2." Pet. 23; *see also id.* at 25. Instead, the Federal Circuit affirmed because, by later claiming genetically engineered antibodies that Chiron clearly had not invented in 1984, Chiron could not rely on the 1984 filing date. Pet. App. 12a-13a. While it is true that the Patent Statute rewards inventors by giving them limited periods of exclusivity for their inventions, it also is true that the Patent Statute prevents patentees from overreaching. *See Vas-Cath*, 935 F.2d at 1563.

Even Chiron's petition demonstrates the inadequacy of the 1984 application for written description purposes. Chiron argues that "[a]cting upon the promise of the Patent Act, petitioner invested substantial time and money to *invent a new, useful antibody target* for the detection and treatment of breast cancer." Pet. 26 (emphasis added). However, Chiron admittedly did not disclose the "antibody target" in the 1984 application. In fact, Chiron could not even identify its "antibody target" until seven years *after* it filed the 1984 application, and it did not disclose the HER2 "antibody target" in a patent application until *eleven years* after filing the 1984 application. *See supra* at 6-7.

4. Chiron further argues that the Federal Circuit required Chiron to describe the "future" in contravention of "the settled interpretation of the enablement requirement" of Section 112. Pet. 26. On the contrary, the Federal Circuit merely required a written description of the broad invention *Chiron* alleged it had invented in 1984: murine, *as well as*

chimeric and humanized, antibodies that bind HER2. Chiron did not describe this broad invention in the 1984 application, and properly lost on written description. *See Vas-Cath*, 935 F.2d at 1564 ("The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*").

5. Finally, Chiron maintains that the Federal Circuit's interpretation of the written description requirement is in tension with Section 120 of the Patent Statute, which authorizes the filing of updated or CIP applications, enlarging an original disclosure to include new technological information. However, Section 120 clearly applies, as Chiron admits, only "if an earlier application adequately disclose[d] an invention." Pet. 28. Here, the Federal Circuit found that the 1984 application did not adequately describe chimeric and humanized antibodies. Indeed, the written description requirement requires a patentee to "convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the invention*." *Vas-Cath*, 935 F.2d at 1563-64 (first emphasis added). The possession function of the written description requirement is fully consistent with the law of CIP applications and Section 120. *See* note 3, *supra*. *See also Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1302 (Fed. Cir. 1999).

## III. OTHER GROUNDS REQUIRE AFFIRMANCE OF THE FEDERAL CIRCUIT'S DECISION.

Even if this Court were to agree with Chiron that there is no separate written description requirement in a priority context, this case would not be over, nor would Chiron be entitled to judgment in its favor. Pet. 12. Rather, at least three alternative grounds require affirmance of the Federal Circuit's decision, making this case a poor vehicle for resolving the questions presented in Chiron's petition. *See Monrosa v. Carbon Black Exp., Inc.*, 359 U.S. 180, 183 (1959).

First, the '561 patent also is invalid under the statutory prohibition against new matter because the Federal Circuit

held that "[t]he 1984 application does not support the new matter added to the '561 patent." Pet. App. 9a. *See* 35 U.S.C. § 132(a). *See also Moba*, 325 F.3d at 1327 (Rader, J., concurring) (if there were no separate written description requirement in a priority context, then all priority issues would be "resolved under the new matter doctrine in 35 U.S.C. § 132.").

Indeed, consistent with his *Moba* concurrence, in this case Judge Rader analyzed whether Chiron satisfied the written description requirement under both Sections 112 and 132. Under either statutory provision, the '561 patent is invalid:

> The written description requirement prevents applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention. *See* 35 U.S.C. § 132. Priority is always a vital issue in patent prosecution procedures—often determining entitlement to an invention. . . . In this case, the Chiron scientists, by definition, could not have possession of, and disclose, the subject matter of chimeric antibodies that did not even exist at the time of the 1984 application. Thus, axiomatically, Chiron cannot satisfy the written description requirement for the new matter appearing in the '561 patent, namely chimeric antibodies.

Pet. App. 13a-14a.

Even Chiron acknowledges that the prohibition against new matter is relevant in a priority context, *i.e.*, when new claims are presented: "Chiron submits . . . that there is no requirement for support for such new claims *beyond the prohibition against new matter* . . . ." Chiron's Brief on Appeal at 22 n.2 (emphasis added).

Second, if this Court were to merge the written description and enablement requirements in a priority context, the Federal Circuit's decision should be affirmed on the ground that Chiron's 1984 application is non-enabling. Judge Bryson already believes that the 1984 application failed to satisfy the enablement requirement, as presently applied. Pet. App. 27a-31a. In his concurring opinion, Judge Bryson observed:

> In this case [] the patentee is not seeking to preserve the validity of its claims by construing them in accordance with the state of the technology at the time of the invention. Instead, Chiron is arguing that the 1984 application provides support for claims covering technology that was not in existence at that time. In that setting, where the claims are accorded a scope that exceeds the scope of enablement, I would hold that the claims are not entitled to priority as of 1984, not only because of a failure to satisfy the written description requirement, but also because the 1984 application does not enable the asserted claims.

*Id.* at 30a-31a. If the written description requirement were merged into the enablement requirement, the enablement requirement would expand to include the present function of written description to prevent patent applicants from overreaching and claiming inventions not in their possession.

Third, Genentech cross-appealed the claim construction of "monoclonal antibody." Under a proper claim construction, one that does not "run afoul of the prohibition against importing new matter into later patent documents," Pet. App. 20a, 35 U.S.C. § 132(a), Genentech does not infringe. The Federal Circuit did not reach the cross-appeal, which it viewed as "an alternative ground for affirming the judgment." Pet. App. 8a. If the '561 patent is not found invalid under either Section 112 or Section 132, then the Federal Circuit, on remand, would address Genentech's cross-appeal of the claim construction, and find no infringement as a matter of law.

## IV. THE FEDERAL CIRCUIT'S DECISION DOES NOT IMPLICATE ANY GENERAL VERDICT RULE.

Chiron last argues that this Court should grant review because the appellate courts, including the Federal Circuit, "continue to avoid the rule adopted by this Court" that a general jury verdict, which may have rested on a theory of liability found erroneous on appeal, cannot stand. Pet. 29. Chiron's makeweight argument does not merit the Court's attention.[9]

Chiron primarily seeks to piggyback on an earlier petition in *Union Pacific Railroad v. Barber*, No. 04-47. According to Chiron, this case presents the same general verdict issue presented by *Union Pacific*. On October 12, 2004, this Court denied the petition in *Union Pacific*, suggesting that the issue does not warrant the Court's attention. *See Union Pac. R.R.*, 356 Ark. 268 (Ark.), *cert. denied*, 125 S. Ct. 320 (2004).

In any event, the Federal Circuit's decision accords with this Court's general verdict precedent. At trial, the district court declined to rule in Chiron's favor as a matter of law because substantial evidence supported that chimeric antibodies were known in 1984. Pet. App. 37a, 55a. Thus, the district court submitted the case to the jury. The court subsequently denied Chiron's renewed motion after trial because substantial evidence supported the verdict. *Id.* at 37a-39a.

On appeal, the Federal Circuit disagreed with the district court about Chiron's knowledge of chimeric antibodies in 1984, Pet. App. 14a, ruling that "[a]t no point did the record show that Chiron scientists actually knew of chimeric antibodies before their filing." *Id.* at. 12a. The Federal Circuit's determination of no substantial evidence allowed the

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[9] Indeed, Chiron did not even object to the general form of the jury's verdict until after the jury ruled in Genentech's favor.

court to rule as a matter of law that the 1984 application did not have to enable chimerics—the future. However, that same determination also allowed the court to rule as a matter of law that the 1984 application did not describe chimeric antibodies:

> [T]he Chiron scientists, *by definition*, could not have possession of, and disclose, the subject matter of chimeric antibodies that did not even exist at the time of the 1984 application. Thus, *axiomatically*, Chiron cannot satisfy the written description requirement for the new matter appearing in the '561 patent, namely chimeric antibodies.

*Id.* at 14a (emphases added). Therefore, this case does not even raise the general verdict argument Chiron advances, because the Federal Circuit ruled in Genentech's favor as a matter of law.

Further, the appellate courts are not ignoring binding precedent, as Chiron alleges. Pet. 29. Rather, the courts have recognized cases in which the alleged error is harmless, and have ruled that, in such instances, the error does not cast doubt on the verdict. *See, e.g.*, *Davis v. Rennie*, 264 F.3d 86, 106-07 (1st Cir. 2001) (holding that harmless error occurs when the court is reasonably certain that the issues erroneously submitted to the jury did not significantly influence it); *Asbill v. Housing Auth. of Choctaw Nation*, 726 F.2d 1499, 1504 (10th Cir. 1984) ("a litmus test for reversal is whether the appellant was thereby unjustly prejudiced."); *see also E.I. duPont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1258 n.8 (8th Cir. 1980); *Kern v. Levolor Lorentzen, Inc.*, 899 F.2d 772, 791 (9th Cir. 1990). The appellate courts are not split or evading this Court's teaching. Rather, they have harmonized this Court's teaching with the harmless error rule. *See* Fed. R. Civ. P. 61. The judicious reconciliation of important governing principles does not necessitate this Court's intervention, even if the general verdict rule were somehow at issue here.

## CONCLUSION

The Court should deny the petition.

Respectfully submitted,

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